

510(k) SUMMARY

MAR 10 2009

COMMWELL LTD.'s PHYSIOGLOVE

A. General Information

- | | |
|----------------------|--|
| 1. Submitter's Name: | Commwell Ltd. |
| 2. Address: | Rechov Yad Harutzim 4 Kfar Saba, Israel 44641 |
| 3. Telephone Number: | 9729-766-8094 |
| 4. Fax number: | 9729-766-8099 |
| 5. Contact Person: | Irving Levy |
| 6. Date Prepared: | December 11, 2008 |

B. Name of Device and Name/Address of Sponsor:

PhysioGlove

Commwell Ltd.
Rechov Yad Harutzim 4
Kfar Saba, Israel 44641

C. Device

- | | |
|-------------------------|------------------------------|
| 1. Trade Name: | PHYSIOGLOVE |
| 2. Common Name: | 12-Lead Diagnostic ECG glove |
| 3. Classification Name: | Electrocardiograph glove |
| 4. Product Code: | DRX |
| 5. Class: | II |
| 6. CFR Reference: | 21 CFR 870.2360 |

D. Predicate devices

- | | |
|---------------|---|
| 1. Name: | Tapuz Medical Technology's ECG Electrodes Apron |
| Date Cleared: | June 1, 2003 and Oct. 14, 1998 respectively |
| 2. Name | IneedMD 12-Lead Glove |
| Date Cleared: | Dec 22, 2004 |

E. Intended Use / Indications for Use

The 12 lead glove is designed to configure the ECG electrodes in a single unit for the purpose of conducting an electrocardiogram. It is for use in patients with a chest girth of 33.5 - 46.5 inches (85 - 118 cms).

F. Technological Characteristics – Components and Safety Features

The PhysioGlove is a glove that incorporates a system of **Ag/AgCl** electrodes for use in recording ECGs. The glove terminates in a standard 15-pin mini D-type connector.

The PhysioGlove is intended to be used with the cleared PhysioGlove ES-1 software, for recording diagnostic 12-lead ECGs.

G. Performance Data

The device was tested according to the following performance standards: IEC 60601-2-25, EC53 and EC 11. In addition, clinical testing was done to demonstrate the efficacy of the PhysioGlove compared to a standard 12-lead ECG cable.

In all instances, the device functioned as intended.

H. Substantial Equivalence

The PhysioGlove is as safe and effective as the Tapuz ECG Electrodes Apron and the IneedMD 12-Lead Glove. The PhysioGlove has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the PhysioGlove and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the PhysioGlove is as safe and effective as the Tapuz ECG Electrodes Apron and the IneedMD 12-Lead Glove. Thus, the PhysioGlove is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 10 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Commwell Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K083677
Trade/Device Name: PhysioGlove
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: Class II
Product Codes: DRX
Dated: December 11, 2008
Received: December 11, 2008

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

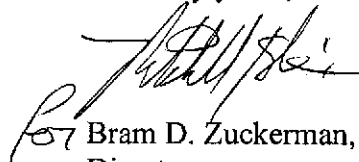
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083677

Device Name: PhysioGlove

Indications for Use:

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Prescription Use ☒
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 C.F.R. 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K083677